

REMARKS

Claims 124, 128, 130, and 143 are amended. Claims 144-146 are new. Claims 124 and 130 are amended by deleting the conventional "packaging" step. Claim 143 is amended by adding the steps of "forming an implant from the cross-linked polyethylene article; and sterilizing the implant using standard means." The amendment to claim 143 is supported by the specification, see for example, page 11, lines 15-22, pages 17-18, Example 20. The term "standard means" added to the claims 124, 130, and 143, and the new dependent claims 144, 145, and 146 is supported by the specification. See for example, specification page 11, lines 20-22; and US Patent No. 5,879,400 (filed February 13, 1996), col. 4, lines 42-44. Claim 128 is amended to rely on applicants' data points. Claim 128 as amended is supported by the specification at, for example, pages 18-19, 29-31, 50-52, and 58-59. New claims 144, 145, and 146 also are supported by the specification as indicated above. Thus, no new matter has been added. Claims 131-142 are cancelled without prejudice or disclaimer. At this time, claims 124-130 and 143-146 remain under examination. Reconsideration and allowance of the claims are earnestly requested.

Enablement Rejections

On pages 2-4 of the office action, the Examiner has rejected claims 124, 128 and 130 under 35 U.S.C. § 112, first paragraph.

Packaging and sterilizing of packaged implants are routine procedures

The Examiner has rejected claims 124 and 130 for describing the step of "packaging the medical implant in an air-permeable package; and sterilizing the packaged implant using non-irradiative methods" and alleged as not being supported by the specification. Applicants disagree with the Examiner and refer to the arguments made in response to the office action of July 8, 2003. Packaging and sterilizing are known requirements of medical implants in order to protect them from the environment prior to implantation. Applicants also note that packaging a medical implant and sterilization of packaged medical implants are conventional procedures in the field and have no patentable significance (see for example, U. S. Patent No. 5,494,162, filed

November 18, 1994; and U. S. Patent No. 5,753,182, filed February 14, 1996, copies of both patents are enclosed). U. S. Patent No. 5,494,162 ("the '162 patent") discloses "medical implant and a package for sterile delivery of the medical implant" (see col. 1 lines 30-66) and "a conventional package for sterile delivery" (col. 3 lines 35-51), for example. The '162 patent discloses packaging and various methods for sterile delivery of medical implants including "a medical implant and a package for sterile delivery of said medical implant, wherein said package comprises a tray defining a compartment...." (col. 6 claim 1). U. S. Patent No. 5,753,182 ("the '182 patent") also discloses packaging of medical implantable component including the steps of packaging the component in a gas permeable container, sterilizing the package component, and exposing the packaged and sterilized component to hydrogen gas or to a gas mixture containing hydrogen (see col. 4 lines 3-12, for example).

Applicants also refer to Dr. Muratoglu's declaration (submitted on October 8, 2003) paragraphs 13-14 that "[s]terilization and packaging are common requirements in the area of UHMWPE medical implants, and have been practiced in the field for decades" and cited the article published by Lewis on air-permeable packaging and sterilization approach (see Robin Lewis, *Medical Device Technology*, 16-25 (January/February 1991)). Therefore, no later than 1991 the standard practice in the field was to place implants in a gas-permeable packaging and then sterilize them with a non-irradiative method.

However, in order to expedite the prosecution, applicants amend claims 124 and 130 by deleting the "packaging" step without prejudice and by replacing the phrase "non-irradiative methods" with "standard means", which includes non-irradiative methods of sterilization (see specification at page 11, lines 20-22, and US Patent No. 5,879,400 (filed February 13, 1996), col. 4, lines 42-44). The use of ethylene oxide is also explicitly described in the instant application at page 11, lines 20-22. Applicants therefore request withdrawal of the enablement rejection.

Claim 128 is enabled by the specification

The Examiner also had rejected claim 128 on enablement grounds based upon the Examiner's view that undue experimentation would be needed to achieve a

crosslinked ultrahigh molecular weight polyethylene (UHMWPE) that has the characteristics recited in the claim. Applicants respectfully disagree with the Examiner and refer to Dr. Muratoglu's declaration (submitted on October 8, 2003) ("the declaration") that addresses copied claim 128 at paragraphs 4-11. The instant specification discloses the starting materials and the production methodologies later disclosed in U.S. Patent Nos. 6,017,975 (Saum '975 patent) and 6,242,507 (Saum '507 patent). Thus, the skilled artisan relying on the captioned application can produce the same cross-linked ultrahigh molecular weight polyethylene disclosed in the Saum '975 and '507 patents and recited in claim 128 without the need for undue experimentation. All that claim 128 did was to set forth some characterization data, and such data is just as dependent on the type of test run as it is on the nature of the composition itself.

In the instant situation, the product and its properties are inseparable, and different types of characterization data are a result of different types of tests being run, rather than differences in the tested composition. Thus, the data set forth in claim 128 is met by practice of an invention disclosed in the captioned application without having to undertake undue experimentation. As explained previously, Dr. Muratoglu supervised an experiment (see paragraphs 8-9 of the declaration), where UHMWPE was irradiated at 175°C with 100 kGY with an electron beam under nitrogen to cross-link, and then aged and tested the cross-linked UHMWPE according to the parameters set forth in claim 128. The cross-linked UHMWPE so produced met the characterization parameters set forth in claim 128. See paragraph 11 of the declaration. Thus, a cross-linked UHMWPE produced according to the teachings of the captioned application possesses the characteristics set forth in claim 128, and therefore the skilled person following the teachings would achieve such a cross-linked UHMWPE without the need to undertake undue experimentation. Applicants also reiterate that similar data for swell ratios of less than 5 are disclosed in Example 4 and Table 6 of the captioned application. In sum, applicants have claimed an embodiment of the invention in the manner permitted by MPEP § 2163.07(a) (Rev. 1, February 2003). Applicants note that the Examiner has not addressed this section of the MPEP. Without acquiescing in the rejection and in the interest of expediting the prosecution, applicants

amend claim 128 to rely on applicants' data. The amendment is supported by the specification (see for example, pages 18-19, pages 29-31, pages 50-52 (Example-11, Tables 8-9), and pages 58-59 (Example-14, Table 17). Applicants, therefore, request withdrawal of the enablement rejection.

Denial of Priority Claim

On page 2 of the office action, the Examiner again denied applicants the right to priority to U.S. application serial no. 08/600,744 on the grounds that the '744 application and the captioned application were "different." Applicants respectfully traverse this determination because being "different" is not a consideration for accordance of priority.

Requirements of priority under U.S. law are set in 35 USC § 120. Section 120 allows priority where claims find support in a previous application that satisfies the first paragraph of 35 USC § 112. As explained in MPEP § 201.11 at 200-63 to 65 (Rev. 1, Feb. 2003), there are six conditions that must be met in order to claim priority, which are as follows:

- A. Support in the parent applications as required by 35 USC §§ 112, 120;
- B. C dependency;
- C. A reference in the specification to the previous applications;
- D. Continuity of inventorship;
- E. Claim for priority must be made within a certain time period; and
- F. An English translation of non-English language priority documents.

Applicants believe that the only requirement that the Examiner questions compliance is condition A, which deals with the first paragraph of 35 USC § 112. The first paragraph of Section 112 contains the (i) written description, (ii) enablement and (iii) best mode requirements. The Examiner appears to have denied priority on the grounds of lack of enablement. See office action dated April 8, 2003 (Paper No. 16) at page 4.

As previously explained, the captioned application is continuation application of a continuation application of a continuation-in-part application of a continuation-in-part application (U.S. Application Serial No. 08/726,313) of the '744 application. The

captioned application also incorporates the entirety of the '744 and '313 applications. The details of the co-pendency chain are set forth in the preliminary amendment of January 19, 2001 and the updated filing receipt, dated July 30, 2001.

Applicants also refer to Dr. Muratoglu's declaration at paragraphs 18 and 19, pages 6 to 20, which provide citation to exemplary support and enabling written description in the priority applications (the '744 and '313 applications, respectively) for all of the claims. The Examiner must consider and address this declaration, which the Examiner has not done to date.

Applicants thus submit that the claims are entitled to the February 13, 1996 and October 2, 1996 priority dates.

Anticipation Rejections

On pages 2-3 of the Office Action, the Examiner has rejected the claims 124-130 and 143 under 35 U.S.C. § 102(a) and alleged as being anticipated by Saum *et al.* (the '975 patent). Applicants disagree with the Examiner and reiterate that the '975 patent is not prior art under 102(a).

Applicants indicate that the earliest possible prior art date for the '975 patent is October 2, 1996 from U.S. Provisional Serial No. 60/027,354.¹ The Examiner applied the '975 patent under 35 USC § 102(a), and the earliest 102(a) date for the '975 patent is the January 25, 2000 issue date, long after applicants' filing dates. Applicants have demonstrated above that the pending claims are entitled to priority dates of February 13, 1996 and October 2, 1996.

First, applicants submit that they are entitled to the first priority date of February 13, 1996, which is over seven months earlier than the October 2, 1996 filing date of the Saum *et al.* provisional application. Thus, the '975 patent is not prior art to the instant claims. Second, the filing date of the '975 application is not prior to applicants' second priority date. Both the Saum *et al.* provisional application (which the Examiner has not

¹The Examiner, however, has not established that the '975 patent is prior art under 35 USC § 102(e) because the Examiner has not analyzed the chain of priority claimed by the '975 patent, and thus has not demonstrated that the '975 patent is entitled to its priority date. See MPEP § 2136 (Rev. 1, February 2003).

demonstrated to be an effective date for section 102(e) purposes) and applicants' second priority date fall on the same date, namely October 2, 1996. The requirements of 35 USC § 102(a) require the prior art to be "before" the invention date of the applicant, which at this stage is based upon the application filing date. Here, the October 2, 1996 filing date of '975 patent is not before applicants' February 13, 1996 and October 2, 1996 filing dates. Accordingly, the '975 patent is not prior art.

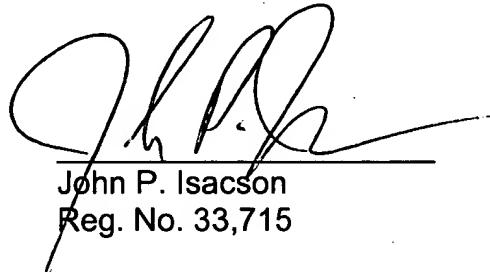
Furthermore, applicants indicate that the Examiner is not entitled to use the '975 patent in a rejection for the following reasons. The '975 patent is the target of applicants' request for interference. A target patent can only be used as a reference against the interfering application if the target patent is a reference under (i) 35 USC § 102(b) or (ii) 35 USC § 102(e) when an applicant has not made a showing as required by 37 CFR § 1.608. See MPEP § 2306 at page 2300-12, column 1 (August 2001). A rejection applying the '975 patent under 35 USC § 102(a), is not permitted.

The '975 patent is not a reference under 35 USC § 102(b) or (e), and applicants have made the requisite showing under 37 CFR § 1.608(a). Accordingly, the rejection should be withdrawn, and the Examiner should take the required steps to propose an interference in accordance with MPEP § 2306.01 (August 2001). In the instant situation, only the Patent Office Board of Appeals and Interferences has the jurisdiction to decide patentability to Saum *et al.* or applicants.

REQUEST RELIEF

Applicants submit that the claims are allowable, and respectfully request an indication to that effect. Applicants further request the application be placed in interference with the '975 patent. If any issues remain which the Examiner believes could be resolved through a Supplemental Response or an Examiner's Amendment, the Examiner is invited to contact the undersigned at 202-912-2000 should there be any questions.

Respectfully submitted,



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November 17, 2004

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